

Beware of Illegally Sold Diabetes Treatments






As the number of people diagnosed with diabetes continues to grow, illegally sold products promising to prevent, treat, and even cure diabetes are flooding the marketplace.

The Food and Drug Administration (FDA) is advising consumers not to use such products. They may contain harmful ingredients or may be otherwise unsafe, or may improperly be marketed as over-the-counter (OTC) products when they should be marketed as prescription products. They carry an additional risk if they cause consumers to delay or discontinue effective treatments for diabetes. Without proper disease management, people with diabetes are at a greater risk for developing serious health complications.

"People with chronic or incurable diseases may feel desperate and become easy prey. Bogus products for diabetes are particularly troubling because there are effective options available to help manage this serious disease rather than exposing patients to unproven and risky products," said Gary Coody, R.Ph., national health fraud coordinator for FDA. "Failure to follow well-established treatment plans can lead to, among other things, amputations, kidney disease, blindness and death."



***Sound too good to be true? Then it's probably a scam.
Watch out for these and similar red flags:***

-  *"Lowers your blood sugar naturally!"*
-  *"Inexpensive therapy to fight and eliminate type II diabetes!"*
-  *"Protects your eyes, kidneys, and blood vessels from damage!"*
-  *"Replaces your diabetes medicine!"*
-  *"Effective treatment to relieve all symptoms of diabetes!"*

Warning Letters Issued

Recently, FDA launched an initiative to counter these illegally sold products aimed at consumers who have diabetes. In addition to evaluating numerous consumer complaints, FDA surveyed the marketplace for illegally sold products promising to treat diabetes and its complications.

In July 2013, FDA issued letters warning 15 companies about selling products for diabetes in violation of federal law. These products are sold as dietary supplements; alternative medicines, such as ayurvedics; prescription drugs and over-the-counter drugs, including homeopathic products. Examples of claims observed on these illegally marketed products include:

- "Lower your blood sugar naturally."
- "Lowers A1C levels significantly."
- "You'll lower your chances of having eye disease, kidney disease, nerve damage and heart disease!"
- "It can replace medicine in the treatment of diabetes."
- "For Relief of Diabetic Foot Pain."

Some of the companies also promote unapproved products for other serious diseases, including cancer, sexually transmitted diseases, and macular degeneration.

FDA tested products marketed as "all natural" treatments for diabetes and discovered some of them contained one or more active ingredients found in prescription drugs to treat type 2 diabetes.

Undeclared ingredients can cause serious harm. If consumers and their health care professionals are unaware of the actual ingredients in the products they are taking, these products may interact in dangerous ways with other medications. One possible complication: Patients may end up taking a larger combined dose of the diabetic drugs than they intended, and that may cause a significant unsafe drop in blood sugar levels, a condition known

as hypoglycemia.

FDA also looked at sales of prescription drugs from fraudulent online pharmacies. Signs that indicate an online pharmacy is legitimate include: requiring that patients have a valid prescription; providing a physical address in the U.S.; being licensed by a state pharmacy board; and having a state-licensed pharmacist to answer questions. Some fraudulent online pharmacies illegally sell drugs that are not approved in the United States, or sell prescription drug products without meeting necessary requirements.

One website that is subject to a warning letter shipped a prescription diabetes drug without requiring a prescription, and even included an unsolicited free sample of a prescription drug for erectile dysfunction. Moreover, the prescription diabetes drug was dispensed without the medication guide and other precautions required by FDA to ensure the drug is used safely and appropriately.

Although some of these websites may offer for sale what appear to be FDA-approved prescription drugs, FDA cannot confirm that the manufacture or the handling of these drugs follows U.S. regulations or that the drugs are safe and effective for their intended uses. Also, there is a risk the drugs may be counterfeit, contaminated, expired or otherwise unsafe.

A Far-Reaching Problem

There are 26 million people in the U.S. who have diabetes, including about 7 million who are undiagnosed, according to the Centers for Disease Control and Prevention. Millions more have pre-diabetes, meaning they have higher than normal blood sugar levels and can reduce their risks of developing diabetes through healthy lifestyle changes, including diet and exercise.

"Products that promise an easy fix might be alluring, but consumers are gambling with their health. In gen-

eral, diabetes is a chronic disease, but it is manageable and people can lower their risk for developing complications by following treatments prescribed by health care professionals, carefully monitoring blood sugar levels, and sticking to an appropriate diet and exercise program," said Coody.

Health care professionals and consumers are encouraged to report any adverse events related to products intended to treat or cure diabetes to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- online at www.fda.gov/Medwatch/report.htm;
- by phone at 800-FDA-1088 (800-332-1088); or,
- by returning FDA form 3500, available on the MedWatch "Download Forms" page (www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm) by mail to the address on the pre-addressed form or by fax at 800-FDA-0178.

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